# PLAINTIFF'S EXHIBIT NO. 18 (03.07.17 HEARING)

Audit Report (New) Created by Lillian Baker on Jan 8, 2014 3:48:27 PM Basic Access Control All Tabs **Last Comment** Number **Document Links** Please Save Liguria Foods, Inc.\_PRJC-491535-2013-MSC-USA # 12687 [rev. 1] (Approved) Company Information Company ID 639356 Company Name Liguria Foods, Inc. Address 1 1515 North 15th Street Address 2 Country UNITED STATES City State/Province **Postal Code** Humboldt lowa 50548 **Certification Body Information CB Name** Det Norske Veritas- DNV Country UNITED STATES Phone +1 708 590 6297 Website Det Norske Veritas- DNV **Audit Information** Audit Reference 13253 **Audit Type** Certification Facility Audit Ed. 7.1 Level 2 **Audit Status** Completed Lead Auditor Secondary Auditor(s) David Williams **Food Sector Categories** 08. Processing of Manufactured Meats and Poultry **Date Audit Started Date Audit Finished** Dec 2, 2013 8:00:00 PM Dec 3, 2013 12:00:00 PM Dec 3, 2013 2:00:00 AM UTC Dec 3, 2013 6:00:00 PM UTC **Audit Rating SQFI Audit Score** G - Good Items Certification Facility Audit Edition 7.1 Module 2 (2)

CONFIDENTIAL

Clause

Opening Meeting

Item

People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by comas)

**Primary Response** 

Compliant

Evidence

Jim Whitham: Director of Quality Control; Brent Heldt: Chilton Consulting Group; David Williams: SQF Auditor

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

Closing Meeting

ltem

People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by comas)

**Primary Response** 

Compliant

Evidence

Jim Whitharm: Director of Quality Control; Brent Heldt: Chilton Consulting Group; Joe Christopherson: V.P. of Operations; Keith Lathrop: Plant Manager; Lance Chambers: CEO; David Williams: SQF Auditor;

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

**Facility Description** 

item

Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details

**Primary Response** 

Compliant

Evidence

The facility has an operational area of 64,000 square feet. The facility employs 91 hourly people and 35 managerial/technical personel. The facility typically runs 5 days per shift with 2 production shifts. The facility is a USDA-inspected facility that produces products for the U.S. market.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

Auditor Recommendation

Item

Auditor Recommendation

Primary Response

Compliant

Evidence

The auditor will recomment the facilty for certification after the successful close-out of the non-conformities.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.1.1.1 Management Policy (2)(M)

ltem

Senior management shall prepare and implement a policy statement that outlines as a minimum the:

i. Organization's commitment to supply safe food;

ii. Methods used to comply with its customer and regulatory requirements and continually improve its food safety management system, and

iii. Organizations commitment to establish and review food safety objectives.

Primary Response

Compliant

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#### Evidence

The facility has a quality policy posted throughout the facility that is signed by senior management and covers all of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.1.1.2 Management Policy (2, 3)(M)

#### Item

The policy statement shall be:

- i. Signed by senior management;
- ii. Made available in language understood by all staff; and
- iii. Displayed in a prominent position and effectively communicated to all staff.

# **Primary Response**

Compliant

#### Evidence

The facility Quality Policy is displayed at the entrances to the production floor and covers all of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.1.2.1 Management Responsibility (1, 2)(M)

#### Item

The organizational reporting structure describing those who have responsibility for food safety shall be defined and communicated within the organization.

## **Primary Response**

Compliant

#### Evidence

The facility has a defined organization struction which is documented in an organizational chart and covers all of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.1.2.2 Management Responsibility (1, 2)(M)

## item

The senior management shall make provision to ensure fundamental food safety practices are adopted and maintained.

## Primary Response

Compliant

## Evidence

Senior management has provided adequate and appropriate resources to cover all of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.1.2.3 Management Responsibility (2)(M)

## ltem

The senior management shall ensure adequate resources are available to achieve food safety objectives and support the development, implementation, maintenance and ongoing improvement of the SQF System.

## **Primary Response**

Compliant

## Evidence

No issues noted with any of the elements of this section. Jim Whitham is the designated and trained SQF Practitioner in the facility. The size and training of the QA staff appeared to be appropriate for the implementation of the SQF system, and the auditor did not see any instance during the audit in which it appeared that the SQF Practitioner did not have access to appropriate resources.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.1.2.4 Management Responsibility (2) (M)

The senior management shall designate an SQF practitioner for each site with responsibility and authority to:

- i. Oversee the development, implementation, review and maintenance of the SQF System, including food safety fundamentals outlined in 2.4.2, and the food safety plan outlined in 2.4.3.
- ii. Take appropriate action to ensure the integrity of the SQF System; and
- iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.

#### Primary Response

Compliant

No issues observed with the support for the SQF Practitioner in his implementation of the SQF system. The facility had engaged a consultant to help prepare for the audit, and those preparations appeared to be relevant and effective.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

2.1.2.5 Management Responsibility (2) (M)

#### ltem

The SQF practitioner shall:

- i. Be employed by the supplier as a company employee on a full-time basis;
- ii. Hold a position of responsibility in relation to the management of the supplier's SQF System;
- iii. Have completed a HACCP training course;
- iv. Be competent to implement and maintain HACCP based food safety plans; and
- v. Have an understanding of the SQF Code level 2 and the requirements to implement and maintain SQF System relevant to the supplier scope of certification.

#### **Primary Response**

Compliant

Jim Whitham is the SQF Practitioner for the facility. Mr Whitham has decades of experience in the industry, has completed the SQF Practitioner course, and has completed a HACCP course. All elements of this section are being met based on interviews with employees, review of records, and observation of the production environment.

Certification Facility Audit Edition 7.1 Module 2 (2)

2.1.2.6 Management Responsibility (2) (M)

The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented.

## Primary Response

Compliant

## Evidence

The facility maintains a training program which includes the training requirements for the SQF system and covers all of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.1.2.7 Management Responsibility (2) (M)

All staff shall be informed of their responsibility to report food safety problems to personnel with authority to initiate action.

# Primary Response Compliant

## Evidence

Interviews with the practitioner and employees verified that all elements of this section are being met.

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.1.2.8 Management Responsibility (2) (M)

Item

Job descriptions for those responsible for food safety shall be documented and include provision to cover for the absence of key personnel.

**Primary Response** 

Compliant

Evidence

No issues noted with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.1.2.9 Management Responsibility (2, 3) (M)

Item

The senior management shall establish processes to improve the effectiveness of the SQF System to demonstrate continuous improvement.

**Primary Response** 

Compliant

Evidence

Interviews with employees, review of the internal audit program, and observation of the production environement verified that all elements of this section are being met.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.1.3.1 Food Safety Management System (2) (M)

Item

A food safety manual shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the organization will use to meet the requirements of this Standard, be made available to staff and include:

i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard;

ii. The policy statement and organization chart;

iii. The scope of the certification; and

iv. A list of the products covered under the scope of certification.

**Primary Response** 

Compliant

Evidence

Auditor review of the Food Safety Manual verified that all elements of this section are being met.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.1.3.2 Food Safety Management System (2, 3) (M)

Item

A food safety manual shall be documented, maintained, made available to relevant staff and include or reference the written procedures, prerequisite programs, food safety plans and other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.

Primary Response

Compliant

Evidence

Auditor review of the food safety manual verified that all elements of this section are being met.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.1.4.1 Management Review (2, 3) (M)

ltem

The senior management shall be responsible for reviewing the SQF System and documenting the review procedure. Reviews shall include: i. The policy manual;

ii. Internal and external audit findings;

iii. Corrective actions and their investigations and resolution; and

iv. Customer complaints and their resolution and investigation.

#### **Primary Response**

Compliant

#### Evidence

Auditor review of the internal audit program, external audit findings, corrective actions, and the customer complaint program verified that all elements of this section are being met.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.1.4.2 Management Review (1, 2, 3) (M)

#### Hem

The SQF System in its entirety shall be reviewed at least annually.

## **Primary Response**

Compliant

#### Evidence

The facility reviewed the elements of the SQF system prior to this audit, and has a system in place to review the system going forward as part of the internal audit program.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.1.4.3 Management Review (2) (M)

#### Item

Food safety fundamentals and food safety plans shall be reviewed when any changes implemented have an impact on the supplier's ability to deliver safe food.

## Primary Response

Compliant

# Evidence

A review of the findings and corrective actions from the audit of the SQF system verified that all elements of this section are being met.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.1.4.4 Management Review (2) (M)

## ltem

The SQF practitioner shall be responsible for validating changes to food safety fundamentals and food safety plans that have an impact on the supplier's ability to deliver safe food.

## **Primary Response**

Compliant

## Evidence

No issues were observed/noted with any of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.1.4.5 Management Review (2, 3) (M)

## Item

Records of all reviews and reasons for amending documents, validations and changes to the SQF System shall be maintained.

## **Primary Response**

Compliant

## Evidence

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Review of records for the SQF review verified that all elements of this section are being met.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.1.5.1 Complaint Management (2, 3)

#### ltem

The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities shall be documented and implemented.

#### Primary Response

Compliant

#### Evidence

Review of the customer complaint program by the auditor verified that all elements of this section are being met.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.1.5.2 Complaint Management (2, 3)

#### Item

Trends of customer complaint data shall be investigated and analyzed by personnel knowledgeable about the incidents

## **Primary Response**

Compliant

#### Evidence

Auditor review of customer complaint records verified that all elements of this section are being met.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.1.5.3 Complaint Management (2, 3)

## Item

Corrective action shall be implemented commensurate with the seriousness of the incident and as outlined under 2.5.5.

## **Primary Response**

Compliant

## Evidence

No issues noted during the review of corrective actions for customer complaints.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.1.5.4 Complaint Management (2)

## Item

Records of customer complaints and their investigations shall be maintained.

## **Primary Response**

Compliant

## **Evidence**

The facility maintains records of customer complaints and investigations.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.1.6.1 Business Continuity Planning (2)

## Item

A business continuity plan based on the understanding of known food safety threats to a business shall be prepared by senior management outlining the methods and responsibility the organization will implement to cope with a business crisis that may impact on the ability of the supplier to deliver safe food.

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# **Primary Response**

Compliant

#### Evidence

No issues noted with any of the elements of this section during the review of the Business Continuity Plan.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.1.6.2 Business Continuity Planning (2, 3)

#### Item

The business continuity plan shall include as a minimum:

- i. A senior manager responsible for decision making, oversight and initiating actions arising from a crisis management incident;
- ii. The nomination and training of a crisis management team;
- iii. The controls implemented to ensure a response does not compromise product safety;
- iv. The measures to isolate and identify product affected by a response to a crisis;
- v. The measures taken to verify the acceptability of food prior to release;
- vi. The preparation and maintenance of a current crisis alert contact list;
- vii. Sources of legal and expert advice; and
- viii. The responsibility for internal communications and communicating with authorities, external organizations and media.

# **Primary Response**

Compliant

#### Evidence

No issues noted with any of the elements of this section during the review of the Business Continuity Plan.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.1.6.3 Business Continuity Planning (2, 3)

#### Item

The business continuity plan shall be reviewed, tested and verified at least annually.

## **Primary Response**

Compliant

## Evidence

No issues noted with any of the elements of this section during the review of the Business Continuity Plan.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.1.6.4 Business Continuity Planning (2, 3)

## Item

Records of reviews and verification of the business continuity plan shall be maintained

## **Primary Response**

Compliant

## Evidence

No issues noted with the records of the Business Continuity Plan.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.2.1.1 Document Control (2, 3) (M)

## Item

The methods and responsibility for maintaining document control and ensuring staff have access to current documents shall be documented and implemented.

## Primary Response

Compliant

## Evidence

All elements of this section are being met.

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Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.2.1.2 Document Control (2, 3) (M)

tem

A register of current SQF System documents and amendments to documents shall be maintained.

**Primary Response** 

Compliant

Evidence

The facility maintains an SQF register of documents that meets all elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.2.1.3 Document Control (2, 3) (M)

Item

Documents shall be safely stored and readily accessible.

Primary Response

Compliant

Evidence

No issues observed with the storage of records.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.2.2.1 Records (2, 3) (M)

Item

The methods and responsibility for undertaking monitoring activities, verifying, maintaining and retaining records shall be documented and implemented.

**Primary Response** 

Compliant

Evidence

The SQF Practitioners is responsible for maintaining records; no issues noted with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.2.2.2 Records (2, 3) (M)

Item

All records shall be legible and suitably authorized by those undertaking monitoring activities that demonstrate inspections, analyses and other essential activities have been completed.

Primary Response

Compliant

Evidence

No issues noted with any of the elements of this section during the review of records.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.2.2.3 Records (2, 3) (M)

item

Records shall be readily accessible, retrievable, securely stored to prevent damage and deterioration and shall be retained in accordance with periods specified by a customer or regulations.

Primary Response

Compliant

CONFIDENTIAL

Evidence

No issues observed with the storage of records.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.3.1.1 Specification and Product Development (2, 3)

Item

The methods and responsibility for designing, developing and converting product concepts to commercial realization shall be documented and implemented.

**Primary Response** 

Compliant

Evidence

No issues noted with any of the elements of this section. The facility maintains specifications for all finished products that are reviewed and approved by the Director of Quality Control (also the SQF Practitioner) and cover all of the requirements of this section.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.3.1.2 Specification and Product Development (2, 3)

ltem

Product formulation, manufacturing processes and the fulfillment of product requirements shall be validated by facility trials, shelf life trials and product testing.

**Primary Response** 

Compliant

Evidence

Review of product development records, specifications, and interviews with employees verified that all elements of this section are being met.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.3.1.3 Specification and Product Development (2, 3)

Item

Shelf life trials where necessary shall be conducted to establish and validate a product's:

i. Handling, storage requirements including the establishment of "use by" or "best before dates";

ii. Microbiological criteria; and

iii. Consumer preparation, storage and handling requirements.

**Primary Response** 

Compliant

Evidence

Random review of product development records and specification did not reveal any issues.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.3.1.4 Specification and Product Development (2)

Item

A food safety plan shall be validated and verified for each new product and its associated process through conversion to commercial production and distribution, or where a change to ingredients, process, or packaging occurs that may impact food safety.

Primary Response

Compliant

Evidence

No issues noted with any of the elements of this section. There had been no major changes to products or processes during the last year.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

CONFIDENTIAL

Clause

2.3.1.5 Specification and Product Development (2, 3)

item

Records of all product design, process development, shelf life trials and approvals shall be maintained.

**Primary Response** 

Compliant

Evidence

No issues noted during any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.3.2.1 Raw and Packaging Materials (2)

ltem

Specifications for all raw and packaging materials, including, but not limited to ingredients, additives, hazardous chemicals and processing aids that impact on finished product safety shall be documented and kept current.

**Primary Response** 

Compliant

Evidence

Random review of specifications, employee interviews, and observation of the production environment did not reveal any issues with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.3.2.2 Raw and Packaging Materials (2, 3)

Item

All raw and packaging materials and ingredients shall comply with the relevant legislation.

**Primary Response** 

Compliant

Evidence

No issues noted with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.3.2.3 Raw and Packaging Materials (2, 3)

Item

The methods and responsibility for developing and approving detailed raw material, ingredient, and packaging specifications shall be documented.

Primary Response

Compliant

Evidence

Review of specifications for ingredients and packaging, employee interviews, and observation of production activities did not reveal any issues.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.3.2.4 Raw and Packaging Materials (2)

Item

Raw and packaging materials and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Validation of raw materials and ingredients shall include Certificate of conformance; or certificate of analysis; or sampling and testing.

**Primary Response** 

Compliant

#### Evidence

No issues noted with any of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.3.2.5 Raw and Packaging Materials (2, 3)

#### Item

Validation of packaging materials shall include:

i. Certification that all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency.

ii. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, tests and analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.

#### **Primary Response**

Compliant

#### Evidence

The facility utilizes letters of guarantee and the supplier approval program to verify that packaging materials are safe and legally compliant.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.3.2.6 Raw and Packaging Materials (2, 3)

#### Item

Product labels shall be accurate, comply with the relevant legislation and be approved by qualified company personnel.

#### Primary Response

Compliant

#### Evidence

No issues noted with any of the elements of this section during the review of labels.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.3.2.7 Raw and Packaging Materials (2, 3)

## Item

A register of raw and packaging material specifications and labels shall be maintained and kept current.

## Primary Response

Compliant

## Evidence

The facility maintains a register of raw and packaging material specifications.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.3.3.1 Contract Service Providers (2)

## Item

Specifications for contract services that have an impact on finished product safety shall be documented, current, include a full description of the service to be provided and detail relevant training requirements of contract personnel.

## **Primary Response**

Compliant

## Evidence

No issues noted with any of the elements of this section during the review of contracted services.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

CONFIDENTIAL

2.3.3.2 Contract Service Providers (2, 3)

Item

A register of all contract service specifications shall be maintained.

**Primary Response** 

Compliant

Evidence

The facility maintains a register of contracted services.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.3.4.1 Contract Manufacturers (2, 3)

Item

The methods and responsibility for ensuring all agreements relating to customers product requirements and its realization and delivery are specified and agreed shall be documented and implemented.

**Primary Response** 

Compliant

Evidence

No issues noted with any of the elements of this section based on review of records and observation of the production environment.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.3.4.2 Contract Manufacturers (2, 3)

ltem

The supplier shall:

i. Verify all customer requirements are being met at all times; and

ii. Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel.

Primary Response

Compliant

Evidence

No issues noted with any of the elements of this section based on record review and auditor observation of the production environment.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.3.4.3 Contract Manufacturers (2, 3)

ltem

Records of all contract reviews and changes to contractual agreements and their approvals shall be maintained.

**Primary Response** 

Compliant

Evidence

No issues noted with the elements of this section based on record review.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.3.5.1 Finished Product (1, 2)

Item

Finished product specifications shall be documented, current, approved by the supplier and their customer, accessible to relevant staff and may include:

i. Microbiological and chemical limits; and

Labeling and packaging requirements.

Primary Response

Compliant

#### Evidence

No issues noted with any of the elements of this section based on random review of specifications by the auditor.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.3.5.2 Finished Product (2, 3)

#### Item

A register of finished product specifications shall be maintained.

#### **Primary Response**

Compliant

#### **Evidence**

The facility maintains a register of finished product specifications.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.4.1.1 Food Legislation (2) (M)

#### Item

The organization shall ensure that, at the time of delivery to its customer, the food supplied shall comply with the legislation that applies to the food and its production in the country of its origin and destination. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, nutritional, allergen and additive labeling, and to relevant established industry codes of practice.

#### **Primary Response**

Compliant

#### Evidence

The facility conducts a pre-shipment review of HACCP records and other elements of the food safety management system as is required by the USDA.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.4.1.2 Food Legislation (2, 3) (M)

## Item

The methods and responsibility for ensuring the organization is kept informed of changes to relevant legislation, scientific and technical developments and relevant industry codes of practice shall be documented and implemented.

## **Primary Response**

Compliant

## Evidence

No issues noted with any of the elements of this section. The SQF Practitioner is responsible for ensuring the food safety management system complies with all relevant legislation and regulatory requirements.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.4.2.1 Food Safety Fundamentals (2) (M)

## Item

The property, buildings and equipment shall be located, constructed, designed and maintained to facilitate the hygienic production, manufacture, handling, storage and/or delivery of safe food. 2.4.2.2 The supplier

# **Primary Response**

Compliant

## Evidence

No issues noted with any of the elements of this section based on auditor observation of the production environment and review of validation records.

Section

CONFIDENTIAL

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.4.2.2 Food Safety Fundamentals (1, 2) (M)

#### Item

The supplier shall ensure the food safety fundamentals described in the relevant subsequent modules of this Code (i.e. modules 3 – 15) are applied or excluded according to a detailed risk analysis outlining the justification for exclusion or evidence of the effectiveness of alternative control measures to ensure that food safety is not compromised.

#### **Primary Response**

Compliant

#### Evidence

No issues noted with any of the elements of this section based on observation of the production environment and review of validation records.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.4.2.3 Food Safety Fundamentals (2, 3) (M)

#### lton

Those pre-requisite programs applicable to the scope of certification that outline the means by which food safety is controlled and assured shall be documented and implemented.

# Primary Response

Minor

#### Evidence

The auditor observed blue tubs that are designated for the storage of edible products being nested in red tubs which are designated for use with inedible products. The practice is in violation of the facility's color-coding policy, which is designed to prevent cross-contamination between inedbile and edible products. No product contamination was observed.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.4.2.4 Food Safety Fundamentals (2, 3) (M)

## Item

The effectiveness of the pre-requisite programs shall be verified as described in 2.5.4.

## **Primary Response**

Compliant

## Evidence

No issues noted based on observation of the production environment, review of records, and employee interviews.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.4.3.1 Food Safety Plan (2, 3) (M)

## Item

A food safety plan shall be developed, effectively implemented, and maintained and outline the means by which the organization controls and assures food safety. The food safety plan shall:

i. Be prepared in accordance with the steps identified in the Codex Alimentanus Commission or NACMCF HACCP guidelines. Primary producers and feed manufacturers may utilize a HACCP-based reference food safety plan developed by a responsible authority.

ii. Cover a product or product group and the associated processes.

iii. Describe the methodology and results of a hazard analysis conducted to identify food safety hazards associated with all inputs and process steps including rework. Animal feed and pet food safety plans must include hazards associated with animal safety as well as the safety of consumers of animal products.

iv. Prescribe those measures taken to apply the controls implemented that are critical to assuring, monitoring and maintaining food safety.

v. Process controls at control points in production to monitor product safety, identify when a process is deviating from set parameters and make corrections to keep a process under control; and

vi. Include documented Standard Operating Procedures (SOPs) and Work Instructions (WI) applicable to the organization's scope of certification.

## **Primary Response**

Compliant

Evidence

CONFIDENTIAL

No issues noted with any of the elements of this section based on review of the HACCP Plan, employee interviews, and observation of the production environment.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.4.5.1 Incoming Goods and Services (2)

#### item

Raw materials, ingredients, packaging materials, and services that impact on finished product safety shall be supplied by an approved supplier.

#### **Primary Response**

Compliant

#### Evidence

No issues observed with any of the elements of this section based on review of the supplier approval program and employee interviews.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.4.5.2 Incoming Goods and Services (2, 3)

#### iten

The receipt of raw materials, ingredients, and packaging materials received from non-approved supplier shall be acceptable in an emergency situation provided they are inspected or analyzed before use.

#### Primary Response

Compliant

#### Evidence

No issues noted with any of the elements of this section based on review of the supplier approval program and employee interviews.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.4.5.3 Incoming Goods and Services (2, 3)

## Item

The responsibility for selecting, evaluating, approving and monitoring an approved supplier shall be documented and implemented.

## **Primary Response**

Compliant

## Evidence

No issues noted with any of the elements of this section based on the review of the supplier approval progam, employee interviews, and review of incoming materials inspections.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.4.5.4 Incoming Goods and Services (2)

## Item

The approved supplier program shall be based on the prior performance of a supplier and the risk level of the raw materials ingredients, packaging materials, and services supplied, and shall contain as a minimum:

# Agreed specifications;

- ii. Reference to the rating of the level of risk applied to a raw material ingredients, packaging materials and services and the approved supplier;
- iii. A summary of the food safety controls implemented by the approved supplier;
- iv. Methods for granting approved supplier status;
- v. Methods and frequency of monitoring approved suppliers;
- vi. Details of the certificates of conformance if required, and
- vii. Methods and frequency of reviewing approved supplier performance and status.

## **Primary Response**

Compliant

## Evidence

No issues noted with any of the elements of this section based on review of the supplier approval program records, observation of the production environment, and employee interviews.

CONFIDENTIAL

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.4.5.5 Incoming Goods and Services (2, 3)

Item

A register of approved supplier and records of inspections and audits of approved suppliers shall be maintained.

**Primary Response** 

Compliant

Evidence

The facility maintains a register of approved suppliers.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.4.6.1 Non-conforming Product or Equipment (2, 3)

Item

The responsibility and methods outlining how non-conforming product, raw material, ingredient, work-in-progress, packaging or equipment detected during receipt, storage, processing, handling or delivery is handled shall be documented and implemented. The methods applied shall ensure:

- i. Non-conforming product is quarantined, identified, handled and disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; and
- ii. Non-conforming equipment is effectively repaired or disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; and
- iii. All relevant staff is aware of the organization's quarantine and release requirements applicable to equipment or product placed under quarantine status.
- iv. For producers, the procedure must document the grower, field name, quantity and final disposition of the unacceptable materials when applicable.

**Primary Response** 

Minor

Evidence

During the review of the Hold Log, the facility could not account for the disposition of one of the items that was selected by the auditor. The item was shown to be on hold, but the facility could not find the product nor was there a documented disposition of the product. The product was on hold for a quality issue, and presented no food safety risk.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.4.6.2 Non-conforming Product or Equipment (2, 3)

lten

Quarantine records, and records of the handling, corrective action, or disposal of non-conforming product or equipment shall be maintained.

**Primary Response** 

Compliant

Evidence

The facility maintains a hold log that records all of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.4.7.1 Product Rework (2, 3)

Item

The responsibility and methods outlining how the product is reworked (recycled or recouped) shall be documented and implemented. The methods applied shall ensure:

i. Reworking operations are supervised by qualified personnel;

ii. Reworked product is clearly identified and traceable;

iii. Each batch of reworked product is inspected or analyzed as required before release;

iv. Inspections and analyses shall conform to the requirements for venfication outlined in element 2.5.6; and

v. Release of reworked product shall conform to element 2.4.8.

**Primary Response** 

Compliant

Evidence

No issues noted with the handling of rework based on review of records and programs along with auditor observation of the production environment.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.4.7.2 Product Rework (2, 3)

tem

Records of all reworking operations shall be maintained.

**Primary Response** 

Compliant

Evidence

Records of rework are maintained by the facility.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.4.8.1 Product Release (2, 3) (M)

Item

The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released:

i. By authorized personnel; and

ii. Once all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met.

**Primary Response** 

Compliant

Evidence

The SQF Practitioner is responsible for managing the Hold Program.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.4.8.2 Product Release (2, 3) (M)

ltem

Records of all product release shall be maintained.

Primary Response

Compliant

Evidence

The supplier maintains a Hold log that documents product release.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.4.9.1 Stock Rotation (2, 3)

Item

The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and implemented.

**Primary Response** 

Compliant

Evidence

No issues observed with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.5.1.1 Responsibility Frequency and Methods (1, 2, 3)

CONFIDENTIAL

#### Item

Validation and verification activities shall be the responsibility of the SQF practitioner.

#### **Primary Response**

Compliant

#### **Evidence**

The SQF Practitioner is responsible for the implementation of validation and verification activities; a review of those activities showed that all elements of this section are being met.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.5.1.2 Responsibility Frequency and Methods (2)

#### Item

The frequency and methods used to validate and verify food safety fundamentals, critical limits, and other food safety controls identified in food safety plans shall be documented and implemented and meet their intended purpose.

## **Primary Response**

Compliant

#### Evidence

Validation activities were found to be relevant and based for the most part on USDA regulatory guidelines; auditor review of validation records, employee interviews, and observation of the production environment verified that all elements of this section are being met.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.5.1.3 Responsibility Frequency and Methods (1, 2, 3)

#### Item

Records of all verification activities shall be maintained.

#### **Primary Response**

Compliant

# Evidence

The facility maintains verification activities, and a review of randomly-selected records verified that verification records are being maintained.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.5.2.1 Validation and Effectiveness (2) (M)

## Item

The methods, responsibility and criteria for ensuring the effectiveness of pre-requisite programs, and validating critical food safety limits to ensure they achieve their intended purpose shall be documented and implemented. The methods applied shall ensure that:

i. Pre-requisite programs are confirmed to ensure they achieve the required result.

- ii. Critical limits are selected to achieve the designated level of control of the identified food safety hazard(s); and
- iii. All critical limits and control measures individually or in combination effectively provide the level of control required.
- iv. Changes to the processes or procedures are assessed to ensure controls are still effective.
- v. Critical food safety limits are re-validated at least annually.

## **Primary Response**

Compliant

## Evidence

Auditor review of the HACCP validation records and validation records of pre-requisite programs verified that all elements of this section are being met.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.5.2.2 Validation and Effectiveness (2, 3) (M)

## Item

Records of all validation activities shall be maintained.

**Primary Response** 

#### Compliant

#### Evidence

Auditor review of validation activities for the food safety management system verified that validation records are being maintained.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.5.3.1 Verification Schedule (1, 2, 3)

#### Item

A verification schedule outlining the verification activities, their frequency of completion and the person responsible for each activity shall be prepared and implemented.

## Primary Response

Compliant

#### Evidence

Verification activities for the food safety management system were completed as part of the preparation for this audit; verification activities are scheduled on a yearly timetable.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.5.4.1 Verification of Monitoring Activities (2) (M)

#### Item

The methods, responsibility and criteria for verifying the effectiveness of monitoring pre-requisite programs critical control points and other food safety controls identified shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each record verified.

#### **Primary Response**

Compliant

#### Evidence

The SQF Practitioner is responsible for implementing verification activities; auditor review of verification records verified that all elements of this section are being met.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.5.4.2 Verification of Monitoring Activities (2, 3) (M)

## Item

Records of the verification of monitoring activities shall be maintained.

## Primary Response

Compliant

# Evidence

Verification monitoring activities are being maintained based on auditor review of randomly-selected records.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.5.5.1 Corrective and Preventative Action (2) (M)

## Item

The responsibility and methods outlining how corrections and corrective actions are investigated, resolved, managed and controlled, including the identification of the root cause and resolution of non-compliance of critical food safety limits, and deviations from food safety requirements, shall be documented and implemented.

# Primary Response

Compliant

# Evidence

Auditor review of corrective actions verified that all elements of this section are being met.

Section

CONFIDENTIAL

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.5.5.2 Corrective and Preventative Action (2, 3) (M)

#### Item

Records of all investigation and resolution of corrections and corrective action shall be maintained.

## **Primary Response**

Compliant

#### Evidence

Auditor review of corrective actions records verified that records are being maintained.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.5.6.1 Product Sampling, Inspection and Analysis (2)

#### Item

The methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work in progress shall be documented and implemented. The methods applied shall ensure:

i. Inspections and analyses are completed at regular intervals as required and to agreed specification and legal requirements;

- ii. Inspections are conducted to ensure raw materials, work in process and finished products comply with the relevant specification, regulatory requirements and are true to label; and
- iii. All analyses are conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods.
- iv. Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard.

## **Primary Response**

Compliant

#### Evidence

Auditor review of product sampling records and employee interviews verified that all elements of this section are being met.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.5.6.2 Product Sampling, Inspection and Analysis (2)

## Item

Records of all inspections and analyses shall be maintained.

# **Primary Response**

Compliant

## Evidence

Auditor review of inspection/analysis records verified that records are being maintained.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.5.7.1 Internal Audits (2) (M)

## Item

The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System including facility and equipment inspections, pre-requisite programs, food safety plans and legislative controls shall be documented and implemented. The methods applied shall ensure:

i. An internal audit schedule is prepared detailing the scope and frequency of internal audits;

ii. Correction and corrective action of deficiencies identified during the internal audits are undertaken;

- iii. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective actions; and
- iv. Records of internal audits and any corrections and corrective action taken as a result of internal audits shall be maintained.

## **Primary Response**

Compliant

## Evidence

Auditor review of internal audit records, employee interview, and observation of the operating environment verified that all elements of this section are being met.

CONFIDENTIAL

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.5.7.2 Internal Audits (2, 3) (M)

Item

Staff conducting internal audits shall be trained in internal audit procedures.

**Primary Response** 

Compliant

Evidence

The supplier maintains an internal audit program that covers all elements of this section are being met.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.5.7.3 Internal Audits (2, 3) (M)

Item

Where possible staff conducting internal Audits shall be independent of the function being audited.

**Primary Response** 

Compliant

Evidence

No issues noted with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.6.1.1 Product Identification (2, 3) (M)

Item

The methods and responsibility for identifying products during all stages of production and storage shall be documented and implemented. The product identification system shall be implemented to ensure:

i. Raw materials, work in progress and finished product are clearly identified during all stages of receipt, production, storage and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements.

Primary Response

Compliant

Evidence

Ingredients, packaging, and finished products were found to be properly identified based on observation of the production environment and employee interviews.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.6.1.2 Product Identification (1, 2, 3) (M)

Item

Product identification records shall be maintained.

Primary Response Compliant

Compilant

Evidence

Auditor review of traceability records verified that identification records are being maintained.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.6.2.1 Product Trace (2, 3) (M)

Item

The responsibility and methods used to trace product shall be documented and implemented to ensure:

i. Finished product is traceable to the customer (one up) and provides traceability through the process to the supplier and date of receipt of raw materials, food contact packaging and materials and other inputs (one back);

ii. Traceability is maintained where product is reworked; and

iii. The effectiveness of the product trace system shall be tested at least annually.

## Primary Response

Compliant

#### Evidence

The facilty maintains a product trace program that covers all elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.6.2.2 Product Trace (1, 2, 3) (M)

#### Item

Records of raw and packaging material receipt and use, and product dispatch and destination shall be maintained.

#### Primary Response

Compliant

#### Evidence

Auditor review of receipt and inspection records verified that records are being maintained.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.6.3.1 Product Withdrawal and Recall (2, 3) (M)

#### Item

The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall:

i. Identify those responsible for initiating, managing and investigating a product withdrawal or recall;

ii. Describe the management procedures to be implemented including sources of legal and expert advice; and

iii. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident.

## **Primary Response**

Compliant

## Evidence

The supplier maintains a recall/withdrawal program that meets all of the requirements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.6.3.2 Product Withdrawal and Recall (2, 3) (M)

## Item

Investigation shall be undertaken to determine the root cause of a withdrawal or recall and details of investigations and any action taken shall be documented.

## Primary Response

Compliant

# Evidence

The facility has recall/withdrawal program that covers all elements of this section are being met; there have been no recalls or withdrawals from this supplier in its history.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.6.3.3 Product Withdrawal and Recall (2, 3) (M)

## ltem

The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually.

# **Primary Response**

Compliant

CONFIDENTIAL

#### Evidence

The supplier conducts mock recalls to verify the effectiveness of the recall program; a review of those mock recalls verified that all elements of this section are being met.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.6.3.4 Product Withdrawal and Recall (2, 3) (M)

Records of all product withdrawals and recalls shall be maintained.

#### **Primary Response**

Compliant

## Evidence

This supplier has never had any product withdrawals/recalls.

Certification Facility Audit Edition 7.1 Module 2 (2)

2.7.1.1 Food Defense (1, 2, 3) (M)

The methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident shall be documented, implemented and maintained.

## **Primary Response**

Compliant

The supplier maintains a food defense program that appeared to be effective based on auditor observation of the facility and employee interviews

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

2.7.1.2 Food Defense (2, 3) (M)

A food defense protocol shall be prepared and include:

- i. The name of the senior management person responsible for food defense:
- ii. The methods implemented to ensure only authorized personnel have access to crops, production equipment and vehicles, manufacturing and storage areas through designated access points;
- iii. The methods implemented to protect sensitive processing points from intentional adulteration;
- iv. The measures taken to ensure the secure storage of raw materials, packaging, equipment and hazardous chemicals;
   v. The measures implemented to ensure harvested crop and/or finished product is held under secure storage and transportation conditions; and
- vi. The methods implemented to record and control access to the premises by employees, contractors, and visitors.

## **Primary Response**

Compliant

Auditor review of the food defense program verified that all elements of this section are being met.

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.8.2.1 Allergen Management (2, 3)

Item

The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include:

i. A risk analysis of those raw materials, ingredients and processing aids, including food grade lubricants, that contain allergens;

ii. A register of allergens which is applicable in the country of manufacture and the country(ies) of destination;

iii. A list of allergens which is accessible by relevant staff.

iv. The hazards associated with allergens and their control incorporated into the food safety plan.

v. Instructions on how to identify, handle, store and segregate raw materials containing allergens provided to staff responsible for receiving those target raw materials.

vi. Provision to clearly identify and segregate foods that contain allergens.

vii. Cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross contact.

viii. Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented.

ix. Separate handling and production equipment where satisfactory line hygiene and clean-up or segregation is not possible.

# Primary Response

Compliant

#### Evidence

The supplier maintains an allergen control program. There are no allergens used as ingredients in the production process; the majority of the requirements in this section are not applicable in this facility.

#### Section

Certification Facility Audit Edition 7.1 Module 2 (2)

#### Clause

2.8.2.2 Allergen Management(1, 2, 3)

#### Item

The product identification system shall make provision for clear identification and labeling in accordance with regulatory requirements of those products produced on production lines and equipment on which foods containing allergens were manufactured.

#### **Primary Response**

N/A

#### Evidence

There are no allergenic ingredients in this facility.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.8.2.3 Allergen Management(1, 2, 3)

## Item

The product trace system shall take into consideration the conditions under which allergen containing foods are manufactured and ensure full trace back of all ingredients used.

## **Primary Response**

Compliant

## Evidence

The supplier maintains an allergen management program; the majority of the section requirments are not applicable because there are no allergens in the facility.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

## Clause

2.8.2.4 Allergen Management (1, 2, 3)

## Item

Re-working of product containing allergen causing agents shall be conducted under conditions that ensure product safety and integrity is maintained. Re-worked product containing allergens shall be clearly identified and traceable.

# **Primary Response**

N/A

## Evidence

There are no allergenic ingredients or finished products in this facility.

## Section

Certification Facility Audit Edition 7.1 Module 2 (2)

CONFIDENTIAL

Clause

2.9.1.1 Training Requirements (2)

Appropriate training shall be provided for personnel carrying out the tasks critical to the effective implementation of the SQF level 2 System and the maintenance of food safety and regulatory requirements.

**Primary Response** 

Compliant

Auditor review of training records and employee interview verified that all elements of this section are being met.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

2.9.2.1 Training Program (2) (M)

An employee training program shall be documented and implemented. It shall outline the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with:

i. Developing and applying Good Agricultural Practices, Good Aquaculture Practices, or Good Manufacturing Practices (as appropriate).

ii. Applying food regulatory requirements;

iii. Steps identified by the hazard analysis and/or other instructions as critical to effective implementation of the food safety plan and the maintenance of food safety; and

iv. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF System.

**Primary Response** 

Minor

Evidence

The facility could not produce evidence of training on the SQF system for one of the employee that was randomly-selected by the auditor.

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.9.3.1 Instructions (2)

Instructions shall be available explaining how all tasks critical to meeting regulatory compliance, the maintenance of food safety and process efficiency are to be performed.

**Primary Response** 

Compliant

Evidence

Auditor review of work instructions and employee interviews did not reveal any issues with any of the elements of this section.

Certification Facility Audit Edition 7.1 Module 2 (2)

2.9.4.1 HACCP Training Requirement (2)

HACCP training shall be provided for staff involved in developing and maintaining food safety plans.

**Primary Response** 

Compliant

**Fvidence** 

Auditor review of training records verified that staff are appropriately trained in the requirements of HACCP.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.9.5.1 Language (1, 2, 3)

Training materials and the delivery of training shall be provided in language understood by staff.

CONFIDENTIAL

**Primary Response** 

Compliant

Evidence

No issues noted with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.9.6.1 Refresher Training (1, 2, 3)

Item

The training program shall include provision for identifying and implementing the refresher training needs of the organization.

**Primary Response** 

Compliant

Evidence

The facility maintains refresher training for employees on a yearly cycle; no issues found with refresher training in the facility.

Section

Certification Facility Audit Edition 7.1 Module 2 (2)

Clause

2.9.7.1 Training Skills Register (2, 3)

Item

A training skills register describing who has been trained in relevant skills shall be maintained. The register shall indicate the:

Participant name;

ii. Skills description;

- iii. Description of the training provided;
- iv. Date training completed;
- v. Trainer or training provider; and
- vi. Supervisor's verification the training was completed and that the trainee is competent to complete the required tasks.

## Primary Response

Compliant

Evidence

The facility maintains a training skills register; auditor review of the register and training records verified that all elements of this section are being met.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.1.1.1 Premises Location

Item

The location of the premises shall be such that adjacent and adjoining buildings, operations and land use do not interfere with safe and hygienic operations.

Primary Response

Compliant

Evidence

No issues observed with the external environment based on auditor inspection and review of pre-requisite programs.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.1.1.2 Premises Location

Item

Measures shall be established to maintain a suitable external environment, and the effectiveness of the established measures shall be monitored and periodically reviewed.

**Primary Response** 

Compliant

Evidence

CONFIDENTIAL

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No issues observed with the external environment based on auditor inspection and review of pre-requisite programs. Inspection of the external environment is part of the internal audit program.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.1.2.1 Construction and Operational Approval

#### Item

The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

#### **Primary Response**

Compliant

#### Evidence

No issues observed with the legality or regulatory approval of the operation.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.1.1 Materials and Surfaces

#### Item

Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging material storage, and cold storage areas shall be constructed of materials that will not contribute a food safety risk.

#### **Primary Response**

Compliant

#### Evidence

The facility is a USDA-regulated facility in good standing that maintains all applicable licenses and approvals.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.2.1 Floors, Drains and Waste Traps

## Item

Floors shall be constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned.

## Primary Response

Compliant

## Evidence

Floors and drains were observed to be appropriate for the production of safe food.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.2.2 Floors, Drains and Waste Traps

## Item

Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or waste water under normal working conditions.

## **Primary Response**

Compliant

## Evidence

No issues with floor drainage were observed in the facility.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.2.3 Floors, Drains and Waste Traps

Item

Drains shall be constructed and located so they can be easily cleaned and not present a hazard.

**Primary Response** 

Compliant

Evidence

No issues were observed with the suitability of the drains in the facility to produce safe food.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.2.2.4 Floors, Drains and Waste Traps

Item

Waste trap system shall be located away from any food handling area or entrance to the premises.

**Primary Response** 

Compliant

**Evidence** 

No issues were observed with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.2.3.1 Walls, Partitions, Doors and Ceilings

Iten

Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be smooth and impervious with a light colored finish, and shall be kept clean (refer 11.2.13.1).

**Primary Response** 

Compliant

Evidence

No issues were observed with any of the elements of this section. There are no drop ceilings in the facility.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.2.3.2 Walls, Partitions, Doors and Ceilings

ltem

Wall to wall and wall to floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

**Primary Response** 

Compliant

Evidence

No issues were observed with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.2.3.3 Walls, Partitions, Doors and Ceilings

Item

Ducting, conduit and pipes that convey services such as steam or water shall be designed and constructed so as to allow ease of cleaning.

**Primary Response** 

Compliant

Evidence

No issues were observed with any of the elements of this section. There are no drop ceilings in the facility.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

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#### 11.2.3.4 Walls, Partitions, Doors and Ceilings

#### Item

Doors, hatches and windows and their frames shall be of a material and construction which meets the same functional requirements for internal walls and partitions.

#### **Primary Response**

Compliant

#### Evidence

The auditor diid not observe any food safety risks with the doors, walls, or windows in the facility.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.3.5 Walls, Partitions, Doors and Ceilings

#### Iton

Food shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products.

## Primary Response

Compliant

#### Evidence

The auditor did not observe any food safety risks with the ceilings in the facility.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.3.6 Walls, Partitions, Doors and Ceilings

#### Item

Drop ceilings shall be additionally constructed to enable monitoring for pest activity, facilitate cleaning and provide access to utilities.

# Primary Response

N/A

## Evidence

The auditor did not observe any drop ceilings in the plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.4.1 Stairs, Catwalks and Platforms

## Item

Stairs, catwalks and platforms in food processing and handling areas shall be designed and constructed so as not to present a product contamination risk, and shall be kept clean (refer to element 11.2.13.1).

## Primary Response

Compliant

## Evidence

No issues were observed with any of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.5.1 Lighting and Light Fittings

## ltem

Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.

## Primary Response

Compliant

## Evidence

Lighting intensity and maintenance was appropriate for the activities conducted in the plant.

CONFIDENTIAL

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.2.5.2 Lighting and Light Fittings

Item

Light fittings in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers and recessed into or fitted flush with the ceiling. Where fittings cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials and addressed in the cleaning and sanitation program.

**Primary Response** 

Compliant

Evidence

Lighting was appropriately protected in the plant so as not to present a food safety risk.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.2.5.3 Lighting and Light Fittings

Item

Light fittings in warehouses and other areas where the product is protected shall be designed such as to prevent breakage and product contamination.

**Primary Response** 

Compliant

Evidence

No issues were observed with regard to lighting in the warehouse.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.2.6.1 Inspection Area

Item

A suitable area within the processing area shall be provided for the inspection of the product if required.

Primary Response

Compliant

Evidence

Inspection areas were appropriately lighted.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.2.6.2 Inspection Area

Item

The inspection area shall be provided with facilities that are suitable for examination of the style of product being processed. The inspection area shall have:

i. Easy access to hand washing facilities; and

ii. Sufficient lighting intensity to enable as thorough inspection of the product as required.

Primary Response

Compliant

Evidence

No issues were observed with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.2.7.1 Dust, Fly and Vermin Proofing

ltem

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All external windows, ventilation openings, doors and other openings shall be effectively sealed when closed and proofed against dust, vermin

## **Primary Response**

Compliant

#### Evidence

No issues were observed with any of the elements of this section. Outside openings were found to be effectively sealed.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

11.2.7.2 Dust, Fly and Vermin Proofing

Personnel access doors shall be provided. They shall be effectively fly-proofed and fitted with a self-closing device.

## **Primary Response**

Compliant

#### Evidence

No issues were observed with any of the elements of this section.

Certification Facility Audit Edition 7.1 Module 11 (2)

11.2.7.3 Dust, Fly and Vermin Proofing

External doors, including overhead dock doors in food handling areas, used for product, pedestrian or truck access shall be fly-proofed by at least one or a combination of the following methods:

- A self-closing device;
- ii. An effective air curtain;
- iii. A fly-proof screen;
- iv. A fly-proof annex.
- v. Adequate sealing around trucks in docking areas

## Primary Response

Compliant

# Evidence

No issues were observed with any of the elements of this section. External doors were appropriately sealed to prevent pest entry.

Certification Facility Audit Edition 7.1 Module 11 (2)

11.2.7.4 Dust, Fly and Vermin Proofing

Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to the product, packaging, containers or processing equipment. Poison bait shall not be used inside ingredient or food storage areas or processing areas.

## **Primary Response**

Compliant

No issues were observed with any of the elements of this section.

Certification Facility Audit Edition 7.1 Module 11 (2)

# Clause

11.2.8.1 Ventilation

Adequate ventilation shall be provided in enclosed processing and food handling areas.

# Primary Response

Compliant

#### Evidence

Ventilation was appropriate in the plant to prevent condensation and other food safety risks.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.8.2 Ventilation

#### Item

Extractor fans and canopies shall be provided in areas where cooking operations are carried out or a large amount of steam is generated and shall have the following features:

- i. Capture velocities shall be sufficient to prevent condensation build up and to evacuate all heat, fumes and other aerosols to the exterior via an exhaust hood positioned over cooker;
- ii. Fans and exhaust vents shall be fly proofed and located so as not to pose a contamination risk; and
- iii. Where appropriate, positive air-pressure system shall be installed to prevent airborne contamination.

#### **Primary Response**

Compliant

#### Evidence

No issues were observed with any of the elements of this section. There are no canopies, fans, or exhaust vents in the facility, and air pressure was appropriate to prevent food safety risks.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.9.1 Premises and Equipment Maintenance

#### Item

The methods and responsibility for the maintenance and repair of plant, equipment and buildings shall be documented, planned and carried out in a manner that minimizes the risk of product, packaging or equipment contamination.

#### **Primary Response**

Compliant

#### Evidence

The plant maintains a Preventive Maintenance plan that covers all of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

# Clause

11.2.9.2 Premises and Equipment Maintenance

## Item

Maintenance staff and contractors shall observe the following practices when undertaking maintenance and repairs in any food processing, handling or storage area:

- i. Routine maintenance of plant and equipment shall be performed according to a maintenance-control schedule and recorded;
- ii. Failures of plant and equipment shall be documented, reviewed and their repair incorporated into the maintenance control schedule;
- iii. Compliance with the personnel and process hygiene requirements (refer to elements 11.3.1, 11.3.2, 11.3.3, 11.3.4) by maintenance staff and contractors;
- iv. Ensure facility supervisors are notified when maintenance or repairs are to be undertaken in any food handling area;
- v. Inform the maintenance supervisor and the facility supervisor if any repairs or maintenance pose a potential threat to product safety (i.e. pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside processing times;
- vi. Remove all tools and debris from any maintenance activity once it has been completed and inform the area supervisor and maintenance supervisor so appropriate hygiene and sanitation can be completed prior to the commencement of facility operations.

# Primary Response

Minor

## Evidence

The PM program covers the majority of equipment in the facility, with the exception of the following items: a) There is no PM schedule for the mixers in the plant. b) The plant could produce only 3 weeks worth of PM records for the Alkar ovens.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.9.3 Premises and Equipment Maintenance

Item

# CONFIDENTIAL

The maintenance schedule shall be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety and quality.

# Primary Response

Compliant

#### Evidence

The facility maintains a variety of maintenance programs including a PM program and pre-requisite programs covering GMPs, handling of maintenance chemicals, and work order protocols.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.9.4 Premises and Equipment Maintenance

#### Iten

Equipment located over product or product conveyors shall be lubricated with food grade lubricants and their use controlled so as to minimize the contamination of the product.

# Primary Response

Compliant

#### Evidence

No issues were observed with the use of lubricants in the plant.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.9.5 Premises and Equipment Maintenance

#### Item

Paint used in a food handling or contact zone shall be suitable for use and in good condition and shall not be used on any product contact surface.

## **Primary Response**

Compliant

## Evidence

No issues were observed with the use of paint in the plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.10.1 Calibration

## Item

The methods and responsibility for the calibration and re-calibration of measuring, test and inspection equipment used for monitoring activities outlined in pre-requisite program, food safety plans and food quality plans and other process controls, or to demonstrate compliance with customer specifications shall be documented and implemented.

## Primary Response

Compliant

## Evidence

The plant maintans a calibration program that covers the ph meters, thermometers, scales, and all other relevant equipment used for measurement in the food safety management system.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.10.2 Calibration

## Item

Procedures shall be documented and implemented to address the disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration state.

# **Primary Response**

Compliant

## Evidence

No issues were observed with any of the elements of this section. Plant requirements to respond to the issues in this section are addressed in the plant's Hold Program, Calibration Program, and HACCP Plan.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.10.3 Calibration

#### Item

Calibrated measuring, test and inspected equipment shall be protected from damage and unauthorized adjustment.

#### **Primary Response**

Compliant

#### Evidence

No issues were observed with any of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.10.4 Calibration

#### Item

Equipment shall be calibrated against national or international reference standards and methods or to accuracy appropriate to its use. In cases where standards are not available, the supplier shall provide evidence to support the calibration reference method applied.

## **Primary Response**

Compliant

#### Evidence

No issues were observed with the calibration methods utilized by this supplier.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.10.5 Calibration

## Item

Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers recommended schedule.

# **Primary Response**

Compliant

## Evidence

No issues were observed with any of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.10.6 Calibration

## Item

Calibration records shall be maintained.

# **Primary Response**

Compliant

## Evidence

No issues were observed with any of the elements of this section based on review of calibration records and employee interviews.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.11.1 Management of Pests and Vermin

Item

The methods and responsibility for integrated pest management shall be documented and effectively implemented. The premises, its surrounding areas, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin.

#### **Primary Response**

Compliant

#### Evidence

No issues were observed with any of the elements of this section based on auditor review of the pest control program and inspection of the plant.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.11.2 Management of Pests and Vermin

#### Item

The pest and vermin management program shall:

- i. Describe the methods and responsibility for the development, implementation and maintenance of the pest and vermin management program;
- ii. Identify the target pests for each pesticide application;
- iii. Outline the methods used to prevent pest problems;
- iv. Outline the pest elimination methods;
- v. Outline the frequency with which pest status is to be checked;
- vi. Include on a site map the identification, location, number and type of bait stations set;
- vii. List the chemicals used (they are required to be approved by the relevant authority and their Material Safety Data Sheets (MSDS) made available);
- viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come in contact with a bait station;
- ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and
- x. Measure the effectiveness of the program to verify the elimination of applicable pests.

## **Primary Response**

Compliant

## Evidence

No issues were observed with any of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.11.3 Management of Pests and Vermin

## Item

Inspections for pest activity shall be undertaken on a regular basis by trained personnel and the appropriate action taken if pests are present.

## Primary Response

Compliant

# Evidence

No issues were observed with any of the elements of this section based on the review of the pest control program and auditor inspection of the plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.11.4 Management of Pests and Vermin

## item

Records of all pest control applications shall be maintained.

## Primary Response

Compliant

## Evidence

No issues were observed with pest control application based on review of pest control records and inspection of the plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.11.5 Management of Pests and Vermin

#### Item

Pesticides and other toxic chemicals shall be clearly labeled and stored as described in element 11.6.4 and handled and applied by properly trained personnel. They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of food and food contact surfaces.

# Primary Response Compliant

#### Evidence

No issues were observed with any of the elements of this section; pesticides are not stored on site and pesticides are only applied by licensed employees of the 3rd party pest control contractor.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

11.2.11.6 Management of Pests and Vermin

#### Item

Pest control contractors shall be:

- Licensed and approved by the local relevant authority;
- ii. Use only trained and qualified operators who comply with regulatory requirements;
- iii. Use only approved chemicals;
- iv. Provide a pest control management plan (see Contract Services 2.3.3) which will include a site map indicating the location of bait stations and
- v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; and
- vi.Provide a written report of their findings and the inspections and treatments applied.

## **Primary Response**

Compliant

No issues were observed with any of the elements of this section based on the review of the pest control program.

Certification Facility Audit Edition 7.1 Module 11 (2)

11.2.11.7 Management of Pests and Vermin

The supplier shall dispose of unused pest control chemicals and empty containers in accordance with regulatory requirements and ensure that:

i. Empty chemical containers are not reused;

ii. Empty containers are labeled, isolated and securely stored while awaiting collection; and

iii. Unused and obsolete chemicals are stored under secure conditions while waiting authorized disposal by an approved vendor.

## **Primary Response**

Compliant

## Evidence

No issues were observed with any of the elements of this section.

Certification Facility Audit Edition 7.1 Module 11 (2)

11.2.12.1 Equipment, Utensils and Protective Clothing

Equipment and utensils shall be designed, constructed, installed, operated and maintained so as not to pose a contamination threat to products.

## **Primary Response**

Compliant

## Evidence

No issues observed with the suitability of the equipment and utensils utilized in the plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.12.2 Equipment, Utensils and Protective Clothing

Item

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Benches, tables, conveyors, mixers, mincers, graders and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious and free from cracks or crevices.

## **Primary Response**

Compliant

#### Evidence

No issues were observed with any of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.12.3 Equipment, Utensils and Protective Clothing

#### Item

Product containers, tubs, bins for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious and readily cleaned. Bins used for inedible material shall be clearly identified.

## Primary Response

Compliant

#### Evidence

No issues were observed with suitability of product containers to produce safe food.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.12.4 Equipment, Utensils and Protective Clothing

#### Item

Waste and overflow water from tubs, tanks and other equipment shall be discharged direct to the floor drainage system.

#### **Primary Response**

Compliant

## Evidence

No issues were observed with any of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.12.5 Equipment, Utensils and Protective Clothing

## ltem

Protective clothing shall be manufactured from material that is not liable to contaminate food and easily cleaned.

## **Primary Response**

Compliant

## Evidence

Protective clothing used in the plant was appropriate to produce safe food.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.12.6 Equipment, Utensils and Protective

## item

Racks shall be provided for the temporary storage of protective clothing when staff leaves the processing area and shall be provided in close proximity or adjacent to the personnel access doorways and hand washing facilities.

## Primary Response

Compliant

## Evidence

No issues were observed with racks used to store temporary clothing.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

11.2.13.1 Cleaning and Sanitation

#### Item

The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities shall be documented and implemented. Consideration shall be given to:

- i. What is to be cleaned;
- ii. How it is to be cleaned;
- iii. When it is to be cleaned;
- iv. Who is responsible for the cleaning;
- v. Methods used to confirm the correct concentrations of detergents and sanitizers, and
- vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

#### **Primary Response**

Compliant

The plant maintains a sanitation program that covers all of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.13.2 Cleaning and Sanitation

Provision shall be made for the effective cleaning of processing equipment, utensils and protective clothing.

#### Primary Response

Compliant

The plant maintains a sanitation program that includes cleaning instructions, training, and verification to ensure equipment is cleaned properly.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

11.2.13.3 Cleaning and Sanitation

Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards and other utensils and for cleaning of protective clothing used by staff. These cleaning operations shall be controlled so as not to interfere with manufacturing operations, equipment or product. Racks and containers for storing cleaned utensils and protective clothing shall be provided as required.

## Primary Response

Compliant

No issues were observed with any of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

11.2.13.4 Cleaning and Sanitation

Pre-operational hygiene and sanitation inspections shall be conducted by qualified personnel to ensure food processing areas, product contact surfaces, equipment, staff amenities and sanitary facilities and other essential reas are clean before the commencement of production.

# Primary Response Compliant

## Evidence

Auditor review of pre-operational records verified that all elements of this section are being met,

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.13.5 Cleaning and Sanitation

CONFIDENTIAL

#### Item

The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared.

- 11.2.13.6 Detergents and sanitizers shall be suitable for use in a food manufacturing environment, and purchased in accordance with applicable legislation. The organization shall ensure:
- i. An inventory of all chemicals purchased and used shall be maintained;
- ii. Detergents and sanitizers are stored as outlined in element 11.6.4:
- iii. Material Safety Data Sheets (MSDS) are provided for all detergents and sanitizers purchased; and
- iv. Only trained staff handles sanitizers and detergents.

#### **Primary Response**

Compliant

#### Evidence

The plant sanitation program covers all elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.2.13.6 Cleaning and Sanitation

#### Itom

Detergents and sanitizers shall be suitable for use in a food manufacturing environment, and purchased in accordance with applicable legislation. The organization shall ensure:

- i .An inventory of all chemicals purchased and used shall be maintained;
- ii. Detergents and sanitizers are stored as outlined in element 11.6.4;
- iii. Material Safety Data Sheets (MSDS) are provided for all detergents and sanitizers purchased; and
- iv. Only trained staff handles sanitizers and detergents.

## **Primary Response**

Compliant

#### Evidence

Auditor review of sanitation chemicals verified that all elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.13.7 Cleaning and Sanitation

## item

The supplier shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that:

- i. Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use;
- ii. Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and
- iii. Unused and obsolete detergents and sanitizers are stored under secure conditions while waiting authorized disposal by an approved vendor.

## **Primary Response**

Compliant

## Evidence

No issues were observed with any of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.2.13.8 Cleaning and Sanitation

## Item

A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.

## Primary Response

Compliant

# Evidence

Auditor review of randomly-selected pre-operational inspection records verified that these records are being maintained by plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

CONFIDENTIAL

#### 11.3.1.1 Personnel

Item

Personnel suffering from infectious diseases or are carriers of any infectious disease shall not engage in product handling or processing operation.

**Primary Response** 

Compliant

Evidence

No issues were observed with health of personnel in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.1.2 Personnel

ltem

Personnel with exposed cuts, sores or lesions shall not be engaged in handling or processing products or handling primary packaging materials or food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored bandage containing a metal strip or an alternative suitable waterproof and colored dressing.

**Primary Response** 

Compliant

Evidence

The facility address these issues in its GMP program, and no issues were observed by the auditor with any of the elements of this section during the audit.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.1.3 Personnel

item

Smoking, chewing, eating, drinking or spitting is not permitted in any food processing or food handling areas.

**Primary Response** 

Compliant

Evidence

These activities are prohibited in the plant GMP program, and no issues were observed by the auditor with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.2.1 Hand Washing

Iten

Hand wash basins shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.

Primary Response

Compliant

Evidence

The plant has adequate hand-washing facilities.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.2.2 Hand Washing

Item

Hand wash basins shall be constructed of stainless steel or similar non-corrosive material and as a minimum supplied with:

i. A potable water supply at an appropriate temperature;

ii. Liquid soap contained within a fixed dispenser;

iii. Paper towels in a hands free cleanable dispenser; and

iv. A means of containing used paper towels.

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Primary Response

Compliant

Evidence

Hand wash facilities are being maintained appropriately in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.2.3 Hand Washing

Itam

The following additional facilities shall be provided in high risk areas:

i. Hands free operated taps; and

ii. Hand sanitizers.

**Primary Response** 

Compliant

Evidence

All hand wash basins in this plant are hands-free, and sanitizers are provided.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.2.4 Hand Washing

Item

A sign instructing people to wash their hands, and in appropriate languages, shall be provided in a prominent position.

**Primary Response** 

Compliant

Evidence

Hand wash signs are posted throughout the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.2.5 Hand Washing

Item

Personnel shall have clean hands and hands shall be washed by all personnel, including staff, contractors and visitors:

On entering food handling or processing areas;

ii. After each visit to a toilet;

iii. After using a handkerchief;

iv. After smoking, eating or drinking; and

v. After handling wash down hoses, dropped product or contaminated material.

**Primary Response** 

Compliant

\_ ..

Employees were observed to wash their hands appropriately in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.2.6 Hand Washing

item

When gloves are used, personnel shall maintain the hand washing practices outlined above.

Primary Response

Compliant

Evidence

No issues were observed with the use of gloves in the plant.

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Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.3.1 Clothing

Item

Clothing worn by staff engaged in handling food shall be maintained, stored, laundered and worn so as not to present a contamination risk to products.

**Primary Response** 

Compliant

Evidence

No issues were observed with employee clothing in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.3.2 Clothing

ltem

Staff engaged in high risk areas shall change into clean clothing or don temporary protective outerwear when entering high risk areas.

**Primary Response** 

Compliant

Evidence

No issues were observed with the clothing used by staff in high-risk areas.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.3.3 Clothing

ltem

Clothing including shoes, shall be clean at the commencement of each shift and maintained in a serviceable condition. Excessively soiled uniforms shall be changed where they present a product contamination risk.

**Primary Response** 

Compliant

Evidence

No issues were observed with the cleanliness of clothing utilized by staff.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.3.4 Clothing

Item

Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area and when damaged. Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area and not on packaging, ingredients, product or equipment.

**Primary Response** 

Compliant

Evidence

No issues were observed with the use of disposable gloves or aprons in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.4.1 Jewelry and Personal Effects

Item

Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or any area where food is exposed. The wearing of plain bands with no stones and medical alert bracelets that cannot be removed can be permitted, however the supplier will need to consider their customer requirements and the applicable food legislation.

#### **Primary Response**

Compliant

#### Evidence

The wearing of jewelry is addressed in the plant GMP plan; no issues were observed with any of the elements of this section.

Certification Facility Audit Edition 7.1 Module 11 (2)

11.3.5.1 Visitors

#### item

All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any food processing or handling area.

## **Primary Response**

Compliant

#### Evidence

No issues were observed with any of the elements of this section; the auditor was required to comply with all GMP requirements while in the facility.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.3.5.2 Visitors

All visitors shall be required to remove jewelry and other loose objects.

## Primary Response

Compliant

## Evidence

No issues were observed with any of the elements of this section; the auditor was required to remove all jewelry before going into the plant.

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.3.5.3 Visitors

Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled or processed.

## **Primary Response**

Compliant

## Evidence

The plant GMP program addresses the prohibition of illness in any person entering the plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

# Clause

11.3.5.4 Visitors

Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all hand washing and personnel practice requirements.

## **Primary Response**

Compliant

No issues were observed with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.6.1 Staff Amenities

ltem

Staff amenities supplied with appropriate lighting and ventilation shall be made available for the use of all persons engaged in the handling and processing of product.

Primary Response

Compliant

Evidence

No issues were observed with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.7.1 Change Rooms

Item

Facilities shall be provided to enable staff and visitors to change into and out of protective clothing as required.

**Primary Response** 

Compliant

Evidence

No issues were observed with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.7.2 Change Rooms

Item

Change rooms shall be provided for staff engaged in the processing of high risk foods or processing operations in which clothing can be soiled.

Primary Response

Compliant

Evidence

No issues were observed with change rooms for staff.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.7.3 Change Rooms

Item

Provision shall be made for staff to store their street clothing and personal items separate from food contact zones and food and packaging storage areas.

**Primary Response** 

Compliant

Evidence

No issues were observed with the storage of personnel items in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.3.7.4 Change Rooms

Item

Where required, a sufficient number of showers shall be provided for use by staff.

Primary Response

N/A

CONFIDENTIAL

## Evidence

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.3.8.1 Laundry

#### Item

Provision shall be made for the laundering and storage of clothing worn by staff engaged in high risk processes and for staff engaged in processing operations in which clothing can be heavily soiled.

## Primary Response

Compliant

#### Evidence

No issues were observed with any of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.3.9.1 Sanitary Facilities

#### Item

Toilet rooms shall be:

- i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations;
- ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room;
- iii. Sufficient in number for the maximum number of staff:
- iv. Constructed so that they can be easily cleaned and maintained; and
- v. Kept clean and tidy.

## **Primary Response**

Compliant

#### Evidence

No issues were observed with the toilet facilities in the plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.3.9.2 Sanitary Facilities

## Item

Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system.

## **Primary Response**

Compliant

## Evidence

No issues were observed with the sanitary drainage in the plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.3.9.3 Sanitary Facilities

## lten

Hand wash basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.2.

## Primary Response

Compliant

## Evidence

Hand wash basins are provided in the toilet rooms.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

## 11.3.10.1 Lunch Rooms

item

Separate lunch room facilities shall be provided away from a food contact/handling zone.

#### **Primary Response**

Compliant

Evidence

No issues were observed with the lunch room facilities in the plant.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.3.10.2 Lunch Rooms

#### Item

Lunch room facilities shall be:

- i. Ventilated and well lit:
- ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting;
- iii. Equipped with a sink serviced with hot and cold potable water for washing utensils;
- iv. Equipped with refrigeration and heating facilities enabling them to store or heat food and to prepare non-alcoholic beverages if required, and
- v. Kept clean and free from waste materials and pests.

## **Primary Response**

Compliant

#### Evidence

No issues were observed with any of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.3.10.3 Lunch Rooms

#### Iten

Signage in appropriate languages instructing people to wash their hands before entering the food processing areas shall be provided in a prominent position in lunch rooms and at lunch room exits.

## **Primary Response**

Compliant

## Evidence

Hand wash signage is found throughout the plant, including outside of lunch rooms.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.3.11.1 First Aid

## Item

First aid facilities shall be provided to treat minor injuries and suitable arrangements shall be provided in circumstances when a patient requires more specialized care.

## Primary Response

Compliant

## Evidence

First aid facilities are provided for employees for minor injuries, and plant is located within a mile of a hospital.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.4.1.1 Staff Engaged in Food Handling and Processing Operations

Item

All personnel engaged in any food handling, preparation or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices:

i. Personnel entry to processing areas shall be through the personnel access doors only;

ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or receiving of product/ingredient/packaging is required;

iii. The wearing of false fingernails or fingernail polish is not permitted when handling food;

- iv. Packaging material, product, and ingredients shall be kept in appropriate containers as required and off the floor;
- v. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate:
- vi. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in section 11.4.1.2.

## Primary Response

Compliant

#### Evidence

No issues were observed with any of the elements of this section; all of these issues are addressed in the plant GMP program.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.4.1.2 Staff Engaged in Food Handling and Processing Operations

#### Item

In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone the supplier shall implement proper controls and procedures to ensure:

i. Food safety is not compromised;

- ii. Sensory evaluations are conducted by authorized personnel;
- iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations;
- iv. Sensory evaluations are conducted in areas equipped for the purpose; and
- v. Equipment used for sensory evaluations is sanitized, maintained and stored separate from processing equipment.

## **Primary Response**

Compliant

# Evidence

No issues were observed with any of the elements of this section; sensory evaluations are conducted off of the production floor.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.4.1.3 Staff Engaged in Food Handling and Processing Operations

## Item

All wash down hoses shall be stored on hose racks after use and not left on the floor.

## Primary Response

Compliant

## Evidence

No issues were observed with the storage of wash down hoses.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.5.1.1 Water Supply

## Item

Adequate supplies of potable water drawn from a known clean source shall be provided for use during processing operations, as an ingredient and for cleaning the premises and equipment.

## **Primary Response**

Compliant

## Evidence

Water potability and temperature was appropriate for the production of safe food.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.5.1.2 Water Supply

CONFIDENTIAL

Item

Supplies of hot and cold water shall be provided as required to enable the effective cleaning of the premises and equipment.

**Primary Response** 

Compliant

Evidence

No issues were observed with the temperature of water used in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.5.2.1 Monitoring Water Microbiology and Quality

Item

Water used for

- i. washing, thawing and treating food;
- ii. an ingredient or food processing aid;
- iii. cleaning food contact surfaces;
- iv. the manufacture of ice; and
- v. the manufacture of steam that will come in contact with food or used to heat water that will come in

contact with food

shall comply with local, national or internationally recognized potable water microbiological and quality standards as required.

**Primary Response** 

Compliant

Evidence

No issues were observed with the use of water in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.5.3.1 Water Delivery

Item

The delivery of water within the premises shall ensure potable water is not contaminated.

Primary Response

Compliant

Evidence

No issues were observed with the delivery of water in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.5.3.2 Water Delivery

Item

The use of non-potable water shall be controlled such that:

i. There is no cross contamination between potable and non-potable water lines;

ii. Non-potable water piping and outlets are clearly identified.

**Primary Response** 

Compliant

Evidence

Non-potable water is not utilized in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.5.4.1 Water Treatment

Item

Water treatment methods, equipment and materials shall be designed, installed and operated to ensure water receives an effective treatment.

**Primary Response** 

N/A

Evidence

The plant does not conduct water treatment for the water utilized in the production process.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.5.4.2 Water Treatment

ltem

Water treatment equipment shall be monitored regularly to ensure it remains serviceable.

Primary Response

N/A

Evidence

Water treatment is not performed in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.5.4.3 Water Treatment

item

Treated water shall be regularly monitored to ensure it meets the indicators specified.

**Primary Response** 

N/A

Evidence

Water treated by the plant is not utilized in the facility.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.5.5.1 Ice Supply

Item

Ice provided for use during processing operations or as a processing aid or an ingredient shall comply with 11.5.2.1.

**Primary Response** 

Compliant

Evidence

No issues observed with the use of ice in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.5.5.2 Ice Supply

iten

Ice rooms and receptacles shall be constructed of materials as outlined in elements 11.2.1, 11.2.2 and 11.2.3 and designed to minimize contamination of the ice during storage and distribution.

Primary Response

. 4//

Evidence

No ice rooms or receptacles were observed in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.5.6.1 Analysis

ltem

Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities and the effectiveness of the treatment measures implemented.

## **Primary Response**

Compliant

#### Evidence

The facility utilizes city water that is tested for potability.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.5.6.2 Analysis

#### Item

Water and ice shall be analyzed using reference standards and methods.

## **Primary Response**

Compliant

#### Evidence

Water is tested externally for potability; no issues noted with the acceptability of the testing.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.5.7.1 Air Quality

#### item

Compressed air used in the manufacturing process shall be clean and present no risk to food safety;

## Primary Response

N/A

#### Evidence

Compressed air is not used on product or product contact surfaces in the plant

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.5.7.2 Air Quality

## Item

Compressed air used in the manufacturing process shall be regularly monitored for purity.

## **Primary Response**

N/A

## Evidence

Compressed air is not used on product or product contact surfaces in the plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.6.1.1 Cold Storage, Freezing and Chilling of Foods

## Item

The supplier shall provide confirmation of the effective operational performance of freezing, chilling and cold storage facilities. Chillers, blast freezers and cold storage rooms shall be:

i. Designed and constructed to allow for the hygienic and efficient refrigeration of food; and

ii. Easily accessible for inspection and cleaning.

## **Primary Response**

Compliant

## Evidence

No issues were observed with the cold storage areas in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.6.1.2 Cold Storage, Freezing and Chilling of Foods

Item

Sufficient refrigeration capacity shall be available to chill, freeze, store chilled or store frozen the maximum anticipated throughput of product with allowance for periodic cleaning of refrigerated areas.

Primary Response

Compliant

Evidence

No issues were observed with refrigeration capacity in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.6.1.3 Cold Storage, Freezing and Chilling of Foods

ltem

Discharge from defrost and condensate lines shall be controlled and discharged to the drainage system.

Primary Response

Compliant

Evidence

No issues were observed with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.6.1.4 Cold Storage, Freezing and Chilling of Foods

Item

Freezing, chilling and cold storage rooms shall be fitted with temperature monitoring equipment and located so as to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible.

**Primary Response** 

Compliant

Evidence

The plant has temperature range requirments for cold storage room, and monitors the rooms to ensure compliance.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.6.1.5 Cold Storage, Freezing and Chilling of Foods

Item

Loading and unloading docks shall be designed to protect the product during loading and unloading.

Primary Response

Compliant

Evidence

No issues were observed with the loading and unloading docks in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.6.2.1 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods

lten

Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration.

**Primary Response** 

Compliant

#### Evidence

No issues were observed with the storage facilities in the plant.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.6.2.2 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods

#### Item

Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin.

#### **Primary Response**

Compliant

## Evidence

Racks were maintained appropriately and did not present a food safety risk in the plant.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.6.2.3 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods

#### Item

Vehicles used in food contact, handling or processing zones or in cold storage rooms shall be designed and operated so as not to present a food safety hazard.

#### **Primary Response**

Compliant

#### Evidence

The auditor did not observe any issues with vehicles used for product conveyance in the plant.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.6.3.1 Storage of Equipment and Containers

## Item

Storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers.

## Primary Response

Compliant

## Evidence

Storage rooms were designed and constructed appropriately.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.6.4.1 Storage of Hazardous Chemicals and Toxic Substances

## Item

Hazardous chemicals and toxic substances with the potential for food contamination shall be stored so as not to present a hazard to staff, product, packaging, product handling equipment or areas in which the product is handled, stored or transported.

## Primary Response

Compliant

## Evidence

The plant has chemical control procedures and a designated area for the storage of chemicals.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.6.4.2 Storage of Hazardous Chemicals and Toxic Substances

ltem

Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

#### Primary Response

Compliant

#### Evidence

No issues were observed with the storage of chemicals/hazardous substances and food items.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.6.4.3 Storage of Hazardous Chemicals and Toxic Substances

#### 140.00

Daily supplies of chemical used for continuous sanitizing of water or as a processing aid, or for emergency cleaning of food processing equipment or surfaces in food contact zones, may be stored within or in close proximity to a processing area provided access to the chemical storage facility is restricted to authorized personnel.

#### Primary Response

Minor

#### Evidence

The auditor observed a cart of sanitation chemicals stored unsecured and unattended outside of the chemical storage area.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.6.4.4 Storage of Hazardous Chemicals and Toxic Substances

#### Itan

Pesticides, rodenticides, fumigants and insecticides shall be stored separate from sanitizers and detergents. All chemicals shall be stored in their original containers.

## **Primary Response**

Compliant

## Evidence

No issues were observed by the auditor with any of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.6.4.5 Storage of Hazardous Chemicals and Toxic Substances

## Item

Hazardous chemical and toxic substance storage facilities shall:

- i. Be compliant with national and local legislation and designed such that there is no cross-contamination between chemicals;
- ii. Be adequately ventilated;
- iii. Be provided with appropriate signage indicating the area is a hazardous storage area;
- iv. Be secure and lockable to restrict access only to those personnel with formal training in the handling and use of hazardous chemicals and toxic substances;
- v. Have instructions on the safe handling of hazardous chemicals and toxic substances readily accessible to staff;
- vi. Be equipped with a detailed and up-to-date inventory of all chemicals contained in the storage facility;
- vii. Have suitable first aid equipment and protective clothing available in close proximity to the storage area;
- viii. In the event of a hazardous spill, be designed such that spillage and drainage from the area is contained; and
- xi. Be equipped with spillage kits and cleaning equipment.

# Primary Response

Compliant

## Evidence

No issues were observed by the auditor with any of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.6.5.1 Alternative Storage and Handling of Goods

Item

Where goods described in 11.6.1 to 11.6.4 are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there is no risk to the integrity of those goods or contamination or adverse effect on food safety and quality.

Primary Response

N/A

Evidence

The auditor did not observe this situation in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.6.6.1 Loading, Transport and Unloading Practices

Item

The practices applied during loading, transport and unloading of food shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported and unloaded under conditions suitable to prevent cross contamination.

Primary Response

Compliant

Evidence

The plant has an incoming ingredient inspection program that is documented, and the auditor observed the shipping/receiving process to be appropriate.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.6.7.1 Loading

item

Vehicles (trucks/vans/containers) used for transporting food shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose and free from odors or other conditions that may impact negatively on the product.

**Primary Response** 

Compliant

Evidence

Auditor review of inspection paperwork and employee interviews verified that the plant has an inspection program for vehicles that covers all of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.6.7.2 Loading

Item

Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity.

Primary Response

Compliant

Evidence

No issues were observed by the auditor with the loading practices in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.6.8.1 Transport

ltem

Refrigerated units shall maintain the food at required temperatures and the unit's temperature settings shall be set, checked and recorded before loading and core product temperatures recorded at regular intervals during loading as appropriate.

**Primary Response** 

Compliant

CONFIDENTIAL

#### Evidence

No issues were observed by the auditor with any of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.6.8.2 Transport

#### Item

The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals and the storage temperature checked at regular intervals during transit.

## **Primary Response**

Compliant

#### Evidence

No issues were observed by the auditor with any of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.6.9.1 Unloading

#### Item

Prior to opening the doors, the refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently and product temperatures shall be recorded at the commencement of unloading and at regular intervals during unloading.

## Primary Response

Compliant

#### Evidence

No issues were observed by the auditor with any of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.6.9.2 Unloading

## Item

Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity.

## Primary Response

Compliant

## Evidence

No issues were observed by the auditor with any of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.7.1.1 Process Flow

## Item

The process flow shall be designed to prevent cross contamination and organized so there is a continuous flow of product through the process. The flow of personnel shall be managed such that the potential for contamination is minimized.

## Primary Response

Compliant

## Evidence

The traffic flow appeared to be appropriate to prevent cross contamination and produce safe food.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.7.2.1 Receipt of Raw and Packaging Materials and Ingredients

CONFIDENTIAL

Item

Dry ingredients and packaging shall be received and stored separately from frozen and chilled raw materials to ensure there is no cross contamination. Unprocessed raw materials shall be received and segregated to ensure there is no cross contamination.

**Primary Response** 

Compliant

Evidence

No issues were observed by the auditor with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.7.3.1 Thawing of Food

Item

Thawing of food shall be undertaken in equipment and rooms appropriate for the purpose.

**Primary Response** 

Compliant

Evidence

No issues were observed by the auditor with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.7.3.2 Thawing of Food

item

Equipment for water thawing shall be continuous flow to ensure the water exchange rate and temperature does not contribute to product deterioration or contamination. Water overflow shall be directed into the floor drainage system and not onto the floor.

**Primary Response** 

N/A

Evidence

There is no water thawing done in the plant.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.7.3.3 Thawing of Food

Item

Air thawing facilities shall be designed to thaw food under controlled conditions at a rate and temperature that does not contribute to product deterioration or contamination.

**Primary Response** 

Compliant

\_ ..

No issues were observed by the auditor with any of the elements of this section.

Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

11.7.3.4 Thawing of Food

item

Provision is to be made for the containment and regular disposal of used cartons and packaging from thawed product so that there is no risk to the product.

**Primary Response** 

Compliant

Evidence

No issues were observed by the auditor with the disposal of packaging.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.7.4.1 High Risk Processes

#### Item

The processing of high risk food shall be conducted under controlled conditions such that:

- i. Sensitive areas in which high risk food has undergone a "kill" step, a "food safety intervention" or is subject to post process handling, are protected/segregated from other processes, raw materials or staff who handle raw materials to ensure cross contamination is minimized; ii. Areas in which high risk processes are conducted are only serviced by staff dedicated to that function;
- iii. Staff access points are located, designed and equipped to enable staff to don distinctive protective clothing and to practice a high standard of personal hygiene to prevent product contamination;
- iv. Product transfer points are located and designed so as not to compromise high risk segregation and to minimize the risk of cross contamination; and
- v. An environmental monitoring program shall be in place for high risk areas. At a minimum, a written procedure detailing the applicable pathogens or indicator organisms to test for that industry, the number of samples to be taken and the frequency of sampling and corrective actions shall be documented. The responsibility and methods shall be documented and implemented. A sampling schedule shall be prepared.

## Primary Response

Compliant

#### Evidence

No issues were observed by the auditor with any of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.7.5.1 Control of Foreign Matter Contamination

#### item

The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented and communicated to all staff.

## Primary Response

Compliant

#### Evidence

No issues were observed by the auditor with any of the elements of this section. The plant has appropriate foreign material controls for the risks in the operating environment.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.7.5.2 Control of Foreign Matter Contamination

## Iten

Inspections shall be performed to ensure plant and equipment remains in good condition and potential contaminants have not detached or become damaged or deteriorated.

## **Primary Response**

Compliant

## Evidence

No issues were observed by the auditor with any of the elements of this section. The plant performs glass and brittle plastic inspections, and the operating environment is inspected for other foreign material risks.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.7.5.3 Control of Foreign Matter Contamination

## Item

The use of temporary fasteners such as string, wire or tape to fix or hold equipment shall not be permitted.

## **Primary Response**

Compliant

## Evidence

The auditor did not observe any use of temporary fasteners or repairs in the plant.

CONFIDENTIAL

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.7.5.4 Control of Foreign Matter Contamination

#### Item

The following preventative measures shall be implemented where applicable to prevent glass contamination:

i. All glass objects or similar material in food handling/contact zones shall be listed in a glass register including details of their location;

- ii. Containers, equipment and other utensils made of glass, porcelain, ceramics, laboratory glassware or other like material (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers or MIG thermometers required under regulation) shall not be permitted in food processing /contact zones;
- iii. Conduct regular inspections of food handling/contact zones to ensure they are free of glass or other like material and to establish no changes to the condition of the objects listed in the glass register; and
- iv. Inspect glass instrument dial covers on processing equipment and MIG thermometers at the start and finish of each shift to confirm they have not been damaged.

#### **Primary Response**

Compliant

#### Evidence

The plant maintains a glass register, and prohibits glass/breakable materials from being brought into the facility.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.7.5.5 Control of Foreign Matter Contamination

#### Item

Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Their condition is subject to regular inspection.

## **Primary Response**

Compliant

#### Evidence

No issues were observed by the auditor with the use of wood in the plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.7.5.6 Control of Foreign Matter Contamination

## Item

Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard.

## **Primary Response**

Compliant

## Evidence

The equipment was observed to be in good condition, and there were no issues with equipment being a potential source of foreign material contamination.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.7.5.7 Control of Foreign Matter Contamination

## item

Knives and cutting instruments used in processing and packaging operations shall be controlled, and kept clean and well maintained.

## Primary Response

Compliant

## Evidence

No issues were observed by the auditor with any of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

Clause

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## 11.7.6.1 Detection of Foreign Objects

#### Item

The responsibility, methods and frequency for monitoring, maintaining, calibrating and using screens, sieves, filters or other technologies to remove or detect foreign matter shall be documented and implemented.

#### **Primary Response**

Compliant

#### Evidence

No issues were observed by the auditor with any of the elements of this section. The facility utilizes metal detectors in the plant to prevent metal in the product.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.7.6.2 Detection of Foreign Objects

#### Item

Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

## **Primary Response**

Compliant

#### Evidence

The plant maintains a metal detection program that is documented. A review of the program and records verified that all elements of this section are being met.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.7.6.3 Detection of Foreign Objects

#### item

Records shall be maintained of the inspection by foreign object detection devices, and their verification.

## Primary Response

Compliant

## Evidence

No issues were observed by the auditor with any of the elements of this section.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.7.7.1 Managing Foreign Matter Contamination Incidents

## Item

In all cases of foreign matter contamination the affected batch or item shall be isolated, inspected, reworked or disposed of.

## Primary Response

Compliant

## Evidence

No issues were observed by the auditor with the handling of potential foreign material contamination based on observation of the operating environment and review of records.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.7.7.2 Managing Foreign Matter Contamination Incidents

## lten

In circumstances where glass or similar material breakage occurs, the affected area is to be isolated, cleaned and thoroughly inspected (including cleaning equipment and footwear) and cleared by a suitably responsible person prior to the commencement of operations.

## **Primary Response**

Compliant

CONFIDENTIAL

#### Evidence

No issues were observed by the auditor with any of the elements of this section based on the review of inspection records, employee interviews, and observation of the production environment.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.8.1.1 Location

#### Iten

On site laboratories shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel.

## **Primary Response**

Compliant

#### Evidence

No issues were observed by the auditor with the management of the laboratory in the plant.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.8.1.2 Location

#### Item

Provisions shall be made to isolate and contain all laboratory waste held on the premises and manage it separately from food waste. Laboratory waste water outlet shall as a minimum be down stream of drains that service food processing and handling areas.

## **Primary Response**

Compliant

#### Evidence

No issues were observed by the auditor with any of the elements of this section.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.8.1.3 Location

## ltem

Signage shall be displayed identifying the laboratory area as a restricted area accessible only by authorized personnel.

## **Primary Response**

Compliant

## **Evidence**

Laboratory access is apppropriately restricted with appropriate signage.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.9.1.1 Dry and Liquid Waste Disposal

## ltem

The responsibility and methods used to collect and handle dry, wet and liquid waste and store prior to removal from the premises shall be documented and implemented.

## **Primary Response**

Compliant

## Evidence

No issues were observed with waste disposal in the plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.9.1.2 Dry and Liquid Waste Disposal

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#### Item

Waste shall be removed on a regular basis and not build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until such time as external waste collection is undertaken.

#### **Primary Response**

Compliant

#### Evidence

No issues were observed with the removal of waste in the plant.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.9.1.3 Dry and Liquid Waste Disposal

#### Item

Trolleys, vehicles waste disposal equipment, collection bins and storage areas shall be maintained in a serviceable condition and cleaned and sanitized regularly so as not to attract pests and other vermin.

## **Primary Response**

Compliant

#### Evidence

No issues were observed with equipment used to transport waste in the plant.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.9.1.4 Dry and Liquid Waste Disposal

#### Item

Adequate provision shall be made for the disposal of all solid processing waste including trimmings, inedible material and used packaging. Waste held on site prior to disposal shall be stored in a separate storage facility and suitably fly proofed and contained so as not to present a hazard.

## **Primary Response**

Compliant

## Evidence

No issues were observed with the provision of resources used to transport waste in the plant.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.9.1.5 Dry and Liquid Waste Disposal

## Item

Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall be either removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal so as not to present a hazard.

## **Primary Response**

Compliant

## Evidence

No issues were observed by the auditor with any of the elements of this section; liquid waste was observed to be disposed of appropriately and without food safety risk.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.9.1.6 Dry and Liquid Waste Disposal

## Item

Reviews of the effectiveness of waste management will form part of daily hygiene inspections and the results of these inspections shall be included in the relevant hygiene reports.

## **Primary Response**

Compliant

#### Evidence

Review of waste disposal effectiveness is part of the plant daily inspection of the operating environment.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.10.1.1 Grounds and Roadways

#### Item

The grounds and area surrounding the premises shall be maintained to minimize dust and be kept free of waste or accumulated debris so as not to attract pests and vermin.

#### **Primary Response**

Compliant

#### Evidence

No issues were observed by the auditor with the maintenance of the plant grounds.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

#### Clause

11.10.1.2 Grounds and Roadways

#### Item

11.10.1.2 Paths, roadways and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operation of the premises.

## **Primary Response**

Compliant

#### Evidence

No issues were observed by the auditor with the maintenance of roadways and paths around the plant.

#### Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.10.1.3 Grounds and Roadways

## Item

11.10.1.3 Surroundings shall be kept neat and tidy and not present a hazard to the hygienic and sanitary operation of the premises.

## **Primary Response**

Compliant

## Evidence

No issues were observed by the auditor with the maintenance of the plant grounds.

## Section

Certification Facility Audit Edition 7.1 Module 11 (2)

## Clause

11.10.1.4 Grounds and Roadways

## Item

Paths from amenities leading to facility entrances are required to be effectively sealed.

## **Primary Response**

Compliant

## Evidence

No issues were observed by the auditor with the maintenance of the paths around the plant.